

III. REMARKS**A. Status of the Claims**

Claims 1-17 are pending. Claim 1 has been amended.

B. Record of Substance of Interview under 37 C.F.R. 1.133

The undersigned wishes to thank the Examiners Micah-Paul Young and Carlos Azpuru for the courtesies extended during the telephone interview held on June 25, 2003 with the undersigned and Benjamin S. DiMarco of the undersigned's office.

During the above-mentioned telephone interview, the Examiner indicated that the present application would be placed in condition for allowance if claim 1 was amended to clarify that the distressing agent is either (i) non-permeant (itself) to human skin; or (ii) is made to be non-permeant to human skin. This change was agreed to be made by amendment to claim 1 to add phrase (ii).

During the interview, the undersigned explained that claim 1 did indeed require the presence of an opioid analgesic and a distressing agent in the claimed composition. The undersigned also explained that the wording recited in the claim after the word "comprises" is actually the body of the claim and not the preamble.

It was agreed that the claims as amended did overcome the Examiner's rejection of claims 1-17 under 35 U.S.C. 103(a) in view of United States Patent No. 5,474,783 to Miranda, et al. (hereafter the Miranda patent). This rejection was set forth at page 4 of the Office Action mailed March 31, 2003.

With respect to claim 1, it was further explained that the distressing substance is non-permeant through the skin. As explained during the interview, examples of possible embodiments falling within the scope of the claim are set forth in the present application at page 5, third paragraph.

It was further explained that the Miranda patent is directed to administering one or more drugs transdermally. It was also explained that to the extent that two drugs can be combined in a formulation, the explanation provided at column 10, lines 43 through 47 is instructive:

"It should be noted that the bioactive agents may be used singly or as a mixture of two or more such agents, and in amounts sufficient to prevent, cure, diagnose or treat a disease, as the case may be.

Exemplary active drugs that can be administered by the novel transdermal drug delivery system of this invention include, but are not limited to: . . . "
(*Emphasis added*)

The distressing agent of the presently claimed invention does not meet all of these criteria, i.e., an agent that is (i) an active drug, (ii) that is administered (iii) transdermally.

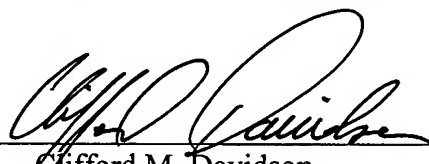
IV. CONCLUSION

By virtue of the present amendment, which includes the limitation added to claim 1, it is respectfully submitted that the present application is in condition for allowance.

No fee is believed due for filing this amendment. If it is determined that a fee is due, the Assistant Commissioner is hereby authorized to charge any fee to Attorney Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Clifford M. Davidson
Reg. No. 32,728

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940